

# Exhibit 7

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Karen M. Williams,  
Magistrate Judge

Honorable Thomas Vanaskie (Ret.),  
Special Discovery Master

**DECLARATION OF SETH A. GOLDBERG**

I, Seth A. Goldberg, of full age, hereby declare as follows:

1. I am an attorney at law of the State of New Jersey, a member of good standing of the bar of this Court, a Partner with the law firm of Duane Morris LLP, and counsel to Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), Prinston Pharmaceutical Inc. (“Prinston”), Solco Healthcare U.S. (“Solco”), and Huahai U.S. Inc. (“Huahai U.S.”, and collectively with ZHP, Prinston, and Solco, “the ZHP Parties”).

2. I make this Declaration based on personal knowledge and in support of the ZHP Parties’ Cross Motion for Protective Order to Preclude the Production of the Custodial File of Baohua Chen.

3. A true and correct copy of the final transcript of Jucai Ge’s deposition testimony on April 30, 2021 is attached to this Declaration as **Exhibit A**.

4. A true and correct copy of the final transcript of Lihong (Linda) Lin’s deposition testimony on May 4, 2021 is attached to this Declaration as **Exhibit B**.

5. A true and correct copy of the final transcript of Min Li's deposition testimony on April 22, 2021 is attached to this Declaration as **Exhibit C**.

6. A true and correct copy of the final transcript of Eric Gu's deposition testimony on April 5, 2021 is attached to this Declaration as **Exhibit D**.

7. A true and correct copy of the final transcript of Hai Wang's deposition testimony on March 11, 2021 is attached to this Declaration as **Exhibit E**.

8. A true and correct copy of the final transcript of John Iozzia's deposition testimony on January 20, 2021 is attached to this Declaration as **Exhibit F**.

9. Attached to this Declaration as **Exhibit G** is a table listing the titles held by Baohua Chen in various public bodies.

10. Attached to this Declaration as **Exhibit H** is an index cataloging the volumes of the ZHP Parties' productions to date in this litigation.

11. Attached to this Declaration as **Exhibit I** is a list of the custodial files collected in connection with the ZHP Parties' productions in this litigation.

12. Attached to this Declaration as **Exhibit J** is a table illustrating the references to Baohua Chen in the exhibits introduced at the depositions of the ZHP Parties witnesses.

13. A true and correct copy of an English language translation of an e-mail dated July 27, 2017, authored by ZHP employee Jinsheng Lin (ZHP00190573) is attached to this Declaration as **Exhibit K**.

14. A true and correct copy of an e-mail dated April 23, 2021 from Plaintiffs' counsel to counsel for the ZHP Parties is attached to this Declaration as **Exhibit L**.

15. A true and correct copy of a declaration executed by Linhong (Linda) Lin, the Director of Regulatory Affairs of ZHP, is attached to this Declaration as **Exhibit M**.

16. A true and correct copy of a declaration executed by Yang Xueyu, a partner of Yu Zheng Law Firm, is attached to this Declaration as **Exhibit N**.

17. Attached to this Declaration as **Exhibit O** is a table comparing the volume of correspondence including Baohua Chen to the total production volume of the ZHP Parties to date in this litigation.

Executed on May 14, 2021.

Respectfully submitted,

/s/ Seth A. Goldberg  
Seth A. Goldberg, Esq.  
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# EXHIBIT K

**Bulletin on the preliminary findings about produced unknown impurities in quenching sodium azide for the crude irbesartan**

**Lin Jinsheng**

July 27, 2017, 4:17 PM Detailed information

To: Ge Jucai, Huang Tianpei, Chen Wangwei, Zhu Wenquan, Chen Wenbin, Li Zong, Dong Peng, Lin Lihong, Liu Yanfeng, Wang Peng, Zhang Wenling  
[icon] Valsartan Impurities K.pdf (846 KB)

General Manager Ge:

According to the results in our telephone communication with the Chuannan (Southern Sichuan)-Technical Department I today, because the separate treatment of sodium azide wastewater of irbesartan resulted in incomplete quenching of sodium azide, resulting in frequent depressed blast in the production process, thus, the technical department carried out technical transformation to quench sodium azide in the no stratification process of the crude irbesartan process, however, after the transformation, 0.544% of unknown impurities are produced in the crude irbesartan at 26 min, and it is the biggest impurity in the crude irbesartan..

[REDACTED]

[REDACTED]

Through the secondary mass spectrometry analysis, it can be inferred that the additional NO substituent is in the cyclic compound fragment part, and it is probably that it is the N-NO compound, similar to the N-nitrosodimethylamine group produced by the quenching of valsartan with sodium nitrite, its structure is very toxic, and its possible production pathways are as follows:



In order to further confirm the structure of the impurity and the principle of its generation, we plan to simulate the quenching conditions to react NaNO<sub>2</sub> and HCl with the finished product of irbesartan, to monitor the impurities produced by the reaction, and then separate them for NMR for final structural confirmation, simultaneously, carry out the confirmation of impurity by multi-stage mass spectrometry.

If it is confirmed as the above speculated structure, its toxicity will be very strong, and GMP risk is great. This is a common problem in the production and synthesis of sartan API. It is recommended to improve to other quenching method, such as NaClO, in addition to optimize the quenching process for sodium azide in valsartan.

Attached is a patent method for quenching sodium azide with NaClO by Xinsaike Pharmaceutical in 2013. they proposed that the use of NaNO<sub>2</sub> quenching will produce N-NO impurities, in the meanwhile, our Huahai crude valsartan was detected by LC-MS. The impurity was indeed found, indicating that other companies have paid attention to this quality issue a long time ago. Leaders are also requested to pay attention to it.

Lin Jinsheng  
CEMAT  
July 27, 2017